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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
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10/736,461

12/15/2003

Jonathan Alexander Terrett

2543-1-034

4511

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7590

08/14/2008

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411 HACKENSACK AVENUE  
HACKENSACK, NJ 07601

EXAMINER

HARRIS, ALANA M

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

08/14/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |   |   |  |
|------------------------------|---|---|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/736,461      | <b>Applicant(s)</b><br>TERRETT, JONATHAN<br>ALEXANDER |  |
|                              | <b>Examiner</b><br>Alana M. Harris, Ph.D. | <b>Art Unit</b><br>1643                               |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-16, 18 and 19 is/are pending in the application.
- 4a) Of the above claim(s) 1-12, 14-16 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13 and 19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Amendment and Arguments***

1. Claims 1-16, 18 and 19 are pending.

Claims 1-12, 14-16 and 18, drawn to non-elected inventions are withdrawn from examination.

Claim 19 has been amended.

Claims 13 and 19 are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Withdrawn Grounds of Rejection***

#### ***Claim Rejections - 35 USC § 112***

3. The rejection of claim 19 under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for compositions comprising antibodies or antigen binding fragments does not reasonably provide enablement for just any antibody fragments is withdrawn in light of Applicants' amendment to claim 19.

### ***Maintained Grounds of Rejection***

#### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

***Claim Rejections - 35 USC § 103***

5. The rejection of claims 13 and 19 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,812,339 (effective filing date October 20, 2000) and in further view of US Patent Application Publication 2005/0159373 A1 (effective filing date March 22, 2001) and Marin et al. (Br. J. Cancer 76(7): 923-9, 1997) is maintained.

Applicants aver the primary reference, patent '339 teaches a number of different sequences and does not teach or suggest any sequence to any specific disease, see page 7 of Remarks submitted May 9, 2008. Applicants assert the Examiner's rejection is simply routine language, which does not provide basis for the instant rejection, see page 8, 1<sup>st</sup> full paragraph. Applicants conclude arguments asserting the secondary references, Marin, nor the patent application publication do not teach or suggest implementing antibodies specific to DTD in therapy and there is no teaching or suggesting in either reference that DTD may be implicated in breast cancers...", see page 8, the last paragraph and page 9, 2nd paragraph of the Remarks. Applicants' arguments and points of view have been carefully considered, but found unpersuasive.

The combination of the references meets all the requirements for a establishing a *prima facie* case of obviousness. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. The patent does such by teaching amino acid sequence 10387 which shares 99.9%

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sequence homology with Applicants' SEQ ID NO: 1. Antibodies directed against amino acid sequences 10387 are recognized as modulators, see column 34, lines 36-41; column 36, line 59-column 37, line 2. These modulators can be administered to treat human disease, see column 35, columns 58-65. Secondary reference, the patent application publication teaches implementing an antibody, as well as fragments and immunoconjugates against the same target sequence for the treatment of breast cancer and Marin teaches the DTD enzyme is associated with breast tumors. Marin et. al. provides the teaching of the importance of DT-diaphorase (DTD) bioreductive drugs for therapeutic use. It is known in the art and exemplified by the publication breast cancer can be effectively treated with antibodies, see abstract; and page 33, sections 0351 and 0352.

The second requirement is there must be a reasonable expectation of success. All three references collectively teach implementing therapeutic antibodies to treat antibodies and the importance of DTD enzyme in breast cancer. The patent and publication provide the success of anti-cancer treatment using therapeutic antibodies against breast cancers, especially when the target is known. This fact assures one of ordinary skill in the art of the high propensity to treat. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on Applicant's disclosure. The Examiner has met the final criteria.

Applicants arguments dependent upon the number of sequences in the primary reference and Marin's teaching "DTD-mediated chemotherapy should be indicated only for individual patients with a demonstrated very high level of activity of this particular enzyme measure in tumor biopsy specimens" does not teach away from the instant rejection, see Remarks, page 8, last paragraph and Marin, page 928, 2<sup>nd</sup> column, last paragraph. The Examiner's statements provided in the last Action mailed December 6, 2007 and the analysis provided in the preceding paragraphs express a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references. For these reasons and those of record the rejection is maintained.

### ***Conclusion***

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alana M. Harris, Ph.D.  
05 August 2008  
/Alana M. Harris, Ph.D./  
Primary Examiner, Art Unit 1643

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|--|-------------------------|---|--|
| <div>Application Number</div> <div></div> | Application/Control No. | Applicant(s)/Patent under Reexamination |  |
|  | 10/736,461              | TERRETT, JONATHAN ALEXANDER             |  |
|  | Examiner                | Art Unit                                |  |
|  | Alana M. Harris, Ph.D.  | 1643                                    |  |
|  |                         |   |  |